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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,462

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EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1627

NOTIFICATION DATE

DELIVERY MODE

04/21/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/567,462	Applicant(s) UENO ET AL.	
	Examiner KENDRA D. CARTER	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-13 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 14-16 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/17/10;10/8/10;3/10/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2010 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of September 10, 2010 made to the office action filed June 9, 2010. Claims 1-24 are pending. Claims 1-8, 10-13 and 17-20 are withdrawn. Claims 21-24 are new. Claims 9, 14-16 and 21-24 are examined on the merits in light of the Applicant's species election of 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF₂ α isopropyl ester in the reply filed on September 17, 2009.

The Declaration was fully considered but was not found persuasive to overcome any of the rejections.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection over Johnstone and Skuballa et al. were found not persuasive, thus the rejection is upheld.

Due to the new amendments to the claims the new and modified 35 U.S.C. 103(a) rejection is repeated below. The Examiner has addressed the Applicant's arguments and Declaration below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 14-16 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnstone (US 6,262,105 B1) in view of Skuballa et al. (US 4,088,775).

Johnstone teach that prostaglandin $\text{PGF}\alpha_2$ compounds stimulate hair growth (see abstract, column 9, lines 1-55 and claim 9; addresses claim 9). Particularly, $\text{PGF}\alpha$ analogues stimulate cell surface receptors, which activate a family of protein kinases that are fundamental in cell growth (see column 8, lines 19-27). $\text{PGF}\alpha$ analogues also alter tensegrity that can direct induction of DNA replication and stimulate cell division, prevention of apoptosis and prolong the hair cycle. By increasing the duration of the cell cycle, the interval in the anagen phase may be increased permitting hypertrophy of the follicles with longer and thicker hairs (see column 8, lines 29-33 and 50-59). The stimulation of hair growth is provided for the hair of the scalp, eyebrows, beard and other areas that contain hair that results in increased hair growth in the corresponding areas (see column 7, lines 60-65; addresses claims 21-25).

Johnstone does not teach the specific elected compound 13,14-dihydro-15,15-ethylenedioxy-20-ethyl $\text{PGF}2\alpha$ isopropyl ester.

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Skuballa et al. teach that compounds like 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF₂ α isopropyl ester (see column 3, lines 1-48) have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract). Particularly, it is generally known that the physiological effects of the prostaglandins are only of short duration in the mammalian organism as well as in vitro, since they are rapidly converted into pharmacologically inactive metabolic products. Thus, a physiologically inactive metabolite is formed by oxidation of the allylic hydroxy function on the C-15 atom (see column 2, lines 21-34). The novel ketals surpass in their activity the natural prostaglandins. Furthermore, the effectiveness lasts over a longer period of time. The 15-ketoprostaglandins corresponding to these ketals show the physiological effects typical for prostaglandins only in greatly weakened form. Therefore, the advantageous properties of the novel compounds could not be expected (see column 2, last paragraph).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teaching of Johnstone and 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF₂ α isopropyl ester because Skuballa et al. teach that compounds such as the elected compound have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract) because they are not easily metabolized (see column 2, lines 21-34) to the inactive prostaglandin. The 15-ketoprostaglandins corresponding to these ketals show the physiological effects typical for prostaglandins only in greatly weakened form.

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Therefore, the advantageous properties of the ketals could not be expected (see column 2, last paragraph). Thus, one skilled in the art would expect 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF₂ α isopropyl ester to have similar activities as taught in Johnstone because it is a PGF₂ α derivative, in which should have better activity as then other PGF₂ α derivatives because of the teachings of Skuballa et al.

Response to Arguments

Declaration

Mr. Tabuchi demonstrates that the applicant's claimed compound, 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF₂ α ethyl ester has superior effect on promoting hair growth than the closest comparison compound from Johnstone, RESCULA (i.e. 13,14-dihydro-15-keto-20-ethyl PGF₂ α isopropyl ester) (see table and page 4, first paragraph).

The Examiner has fully considered the declaration but does not find the results persuasive to overcome the rejections. Particularly, the comparison compound is not mentioned in Johnstone and thus can not be the closest comparison to the Applicant's claimed compound. Johnstone teaches several compounds that possess hair growth activity (see claim 9), particularly that the carbon can have more than one hydroxyl group attached to it. Additionally, the Declaration is completely ignoring the teaching of Skuballa et al. which provides clear motivation to make the ketal analogue because it is superior to the hydroxyl or the carbonyl at the 15-position. Further, the results only demonstrate "superior" results for concentration ranges of 0.01% and 0.02%, in which

the current claims are drawn to any amount of the compounds providing superior results.

Rejection

The Applicant argues that intraocular pressure (IOP) is highly relevant, contrary to the Examiner's arguments to the previous Declaration. Particularly, when applied on eyelashes, the IOP lowering effect is clearly an unwanted side effect that should be avoided. Thus the elected compound provides unexpectedly superior results of not lowering the IOP. Further, the elected species demonstrates superior hair growth promoting effects over the Johnstone compound. Additionally, the working examples in Johnstone use latanoprost which is a very different structure from the elected species. It would appear that one skilled in the art would explore compounds among those having IOP lowering effect in view of how the invention of Johnstone was discovered.

The Examiner disagrees for the same reason as given in for the arguments toward the presently filed Declaration. One skilled in the art would be motivated to use the Applicant's elected compound over the compounds of Johnstone because Skuballa et al. teach that compounds such as the elected compound have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract). Particularly, the compounds like the Applicant's elected compounds are not easily metabolized (see column 2, lines 21-34) to the inactive prostaglandin. Skuballa et al. provides clear motivation to make the ketal analogue because it is superior to the hydroxyl or the carbonyl at the 15-position. Thus, one skilled in the art would expect 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF₂ α isopropyl ester to have similar activities as taught in Johnstone because it is a PGF₂ α derivative, in which should have better activity as then other PGF₂ α derivatives taught

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in claim 9 of Johnstone because of the teachings of Skuballa et al. The teachings of Johnstone are not limited to the examples. The claims clearly cover the applicant's compounds, while Skuballa et al. provides the motivation to make the elected ketal. Regarding the IOP effect, this effect may not deter one skilled in the art to use the compounds since Johnstone apparently teaches that these compounds are effective in growing hair even with this effect. Sometimes side effects are tolerated because of the usefulness of the treatment. Additionally, reduced IOP is useful in the population of patients that have glaucoma (see Johnstone, column 3, lines 50-56). Further, the present invention and Johnstone is not limited to the growth of eyelashes. The composition of Johnstone can be used as creams and applied to the scalp and other areas that hair grows. Likewise, the Applicant's invention is not limited to eyelash growth.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kendra D Carter
Examiner, Art Unit 1627

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627